

**Analysis of Initially Isolated Formulations of PMN Substance Required
Under Consent Order PMN P-11-0091, P-11-0092, and P-11-0093**

Annual Report

August 11, 2018 – August 10, 2019 Analytical Summary

Prepared by:

October 2019

Report P-10-19-10

Table of Contents

Objective	3
Materials and Methods.....	4
A. Samples Analyzed.....	4
Initially Isolated Formulations of the PMN Substance.....	4
B. Analytical Methods.....	4
Analytical Method for Initially Isolated Formulations of the PMN Substance	4
Results.....	5
Analysis of Initially Isolated Formulations of the PMN Substance	5
Conclusion	5

Objective

Consent order P-11-0091, P-11-0092, P-11-0093 requires the Company to analyze representative samples of the initially isolated formulation(s) of the PMN substance at each manufacturing facility for the analytes specified in Table 3 of the consent order and report the results at initial commencement of manufacture or import and again if any new manufacturing facility is added or if the process of manufacture of the PMN substance or any intermediate thereof is significantly altered. The Company is also required to annually analyze the initially isolated formulation(s) and report these results to EPA, in a cycle complementary to the

In addition to the annual reporting for the initially isolated formulation(s) of the PMN substance, the Company must annually report for the starting material: (1) the average values and range of values, including outlying data, from the routine analyses for the analytes specified in Table 1 of the consent order and (2) the results of the annual analysis for the analyte specified in Table 2 of the consent order. This report covers the annual reporting requirements for the initially isolated formulations of the PMN substance only. The starting material results are provided in a separate report because the starting material is common to PMN substances manufactured under several different consent orders. The starting material results can be found in Report P-10-19-02 entitled, “Analysis of Under Consent Orders: P-07-0087; P-08-0200; P-08-0643, P-08-0642, P-08-0644, and P-08-0664; P-08-0748 and P-08-0751; P-09-0245 and P-09-0246; P-09-0293 and P-09-0294; P-10-0058, P-10-0059, and P-10-0060; P-10-0148; P-11-0091, P-11-0092, P-11-0093, and P-12-0450”

Materials and Methods

A. Samples Analyzed

Initially Isolated Formulations of the PMN Substance

In this reporting period for the manufacture of the PMN substances covered under the subject consent order, there have been one (1) initially isolated formulations of the P-11-0091 substance manufactured. They are as follows:

The initially isolated formulations of the PMN substance listed above were packed out between August 11, 2018 and August 10, 2019. As per the consent order P-11-0091, P-11-0092, P-11-0093, representative samples of these formulations were analyzed for the substances specified in Table 3 of the consent order and reported to EPA at the time of first commercial manufacture or import, and again if any new manufacturing facility was added or if the process of manufacture of the PMN substance or any intermediate thereof was significantly altered, or at least annually in this report.

B. Analytical Methods

Analytical Methods for Initially Isolated Formulations of the PMN Substance

Representative samples of the initially isolated formulations of the PMN substance were analyzed for the analytes specified in Table 3 of the P-11-0091, P-11-0092, P-11-0093 consent order using methods described in detail in Report P-10-19-01 entitled: “Analytical Methods for the Analysis of _____ and Initially Isolated Formulations of the PMN Substances Required Under Consent Orders: P-07-0087; P-08-0200; P-08-0643, P-08-0642, P-08-0644, and P-08-0664; P-08-0748 and P-08-0751; P-09-0245 and P-09-0246; P-09-0293 and P-09-0294; P-

10-0058, P-10-0059, and P-10-0060; P-10-0148; P-11-0091, P-11-0092, P-11-0093, and P-12-0450.”

Results

Analysis of Initially Isolated Formulations of the PMN Substance

The results for analytes specified in Table 3 of the consent order are presented in Table 1 below.

LOT #	Product	conc (%)	conc (%)	conc (ppm)
	(estimated Max)	0.7% max combined	0.1% max combined	2 ppm max
13J		<0.0002	<0.0002	<0.5
S81.18J		<0.0002	<0.0002	<0.5
L09.19J		<0.0002	<0.0002	<0.5
S43.19J		<0.0002	<0.0002	<0.5
Avg		<0.0002	<0.0002	<0.5
Range		<0.0002 -- <0.0002	<0.0002 -- <0.0002	<0.5 -- <0.5

Table 1

Conclusion

The analyses specified in the consent order P-11-0091, P-11-0092, P-11-0093 have been completed for representative samples of the initially isolated formulations of the PMN substance manufactured between August 11, 2018 and August 10, 2019. The Company is required to annually analyze representative samples of the initially isolated formulation(s) and report these results to EPA, in a cycle complementary to the

This report fulfills this requirement.